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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,368	12/12/2003	Per Sauerberg	6594.200-US	2809

23650 7590 11/07/2008
NOVO NORDISK, INC.
INTELLECTUAL PROPERTY DEPARTMENT
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PRINCETON, NJ 08540

EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

NOTIFICATION DATE	DELIVERY MODE
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11/07/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/734,368	Applicant(s) SAUERBERG ET AL.	
	Examiner ROSALYND KEYS	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48, 53-66 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 is/are rejected.
- 7) ☒ Claim(s) 58, 59, and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-8,12-15,23,25,29-31,35-37,53,55-57,60,62 and 70-73.

DETAILED ACTION

Status of Claims

1. Claims 1-48, 53-66, 69-73 are pending.

Claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 are rejected.

Claims 5-8, 12-15, 23, 25, 29-31, 35-37, 53, 55-57, 60, 62 and 70-73 are withdrawn from consideration.

Claims 58, 59, and 61 are objected.

Claims 49-52, 67, and 68 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 14, 2008 has been entered.

Election/Restrictions

3. Claims 5-8, 12-15, 23, 25, 29-31, 35-37, 53, 55-57, 60, 62 and 70-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 20, 2006.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 are rejected under 35 U.S.C. 103(a) as obvious over Sauerberg et al. (WO 01/79150 A1) in view of Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al. (US 6,200,995 B1).

Sauerberg et al. teach the claimed invention at page 3, line 16 to page 4, line 4; page 8, line 1 to page 10, line 3; page 15, line 20 to page 16, line 15; and page 17, lines 23-31. In the compound of general formula (I) the Y substituent corresponds to T-Z-U in the instant compound of formula (I). Sauerberg et al. disclose that Y is alkylaralkyl (see page 3, line 28). Examples of alkyl include methyl, ethyl and isopropyl (see page 4, lines 29 and 30). Examples of aryl include phenyl, naphthyl and the like (see page 5, lines 21-23). The phrase "and the like" is suggestive of using other known aryl groups including divalent polycyclic ring-systems (see page 5, lines 21-23 and page 6, lines 1-3).

Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al. (US 6,200,995 B1) each relate to compounds which are PPAR agonists or modulators (see entire disclosures, in particular the background of invention for each reference).

De la Brouse-Elwood et al. define aryl to mean phenyl, 1 or 2-naphthyl, 4-biphenyl, etc. (see column 4, lines 12-34).

Pershadsingh et al. define aryl to mean phenyl, naphthyl, biphenyl, etc. (see column 5, lines 1-16).

One having ordinary skill in the art at the time the invention was made would reasonably have believed that the phrase "and the like" as disclosed by Sauerberg et al. would include biphenyl or other divalent polycyclic ring-systems as disclosed by

Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al., since these were common aryl substituents for compounds which are PPAR modulators or agonists.

Allowable Subject Matter

8. Claims 58, 59 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lou et al. (US 2002/0082263 A1) teach compounds which are PPAR-gamma selective agonists (see the entire disclosure). Lou et al. teach that the term aryl represents an unsubstituted, mono-, di- or trisubstituted monocyclic, polycyclic, biaryl aromatic groups covalently attached at any ring position capable of forming a stable covalent bond, certain preferred points of attachment being apparent to those skilled in the art. Lou et al. further teach that the definition of aryl includes but is not limited to phenyl, biphenyl, indenyl, fluorenyl, naphthyl (see paragraph 0062).

Houze et al. (US 2002/0120137 A1) teach compounds and pharmaceutical compositions that are useful in modulating the farnesoid X receptor (FXR) (see entire disclosure). It is taught that the modulation of the level of FXR activity in cells has a wide range of effects on a variety of biological processes which are mediated by RXR or

other RXR-interacting proteins such as PPAR γ and PPAR α (see abstract). It is further taught that non-limiting examples of aryl include phenyl, 1-naphthyl, 2-naphthyl, 4-biphenyl, ... (see paragraph 0076).

McGee et al. (US 2002/0169185 A1) teach compounds and compositions that are useful in the treatment or prevention of a condition or disorder mediated by PPAR γ (see entire disclosure). It is taught that aryl means an aromatic substituent which can be a single ring or multiple rings which are fused together or linked covalently. Non-limiting examples of aryl groups include phenyl, 1-naphthyl, 2-naphthyl, 4-biphenyl, (see paragraph 0028).

Response to Arguments

10. Applicant's arguments filed October 14, 2008 have been fully considered but they are not persuasive.

The Applicants argue that the amendment filed April 28, 2008 changed the claims and as such all claims are not currently drawn to the same invention as was claimed prior to the entry of the submission under 37 CFR § 1.114.

This argument is not persuasive because the amendments to the claims did not include subject matter that was not in the previous claims.

The Applicants argue that all the claims could not be finally rejected on the grounds of record, as the grounds of record were withdrawn and a new rejection was issued in the instant office action.

The argument is not persuasive because the only ground of rejection that was withdrawn was the rejection of claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 under 35 U.S.C. 102(b) as anticipated by Sauerberg (WO 01/79150 A1). The rejection of claims 1-4, 9-11, 16-22, 24, 26-28, 32-34, 38-48, 54, 63-66 and 69 under 35 U.S.C. 103(a) as obvious over Sauerberg et al. (WO 01/79150 A1) in view of Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al. (US 6,200,995 B1) was maintained for the same reasons as the previous office action, mailed November 27, 2007.

The Applicants argue that based upon the teachings in Pershadsingh et al. the aryl in Sauerberg does not include groups such as biphenyl.

This argument is not persuasive because regardless of whether an additional substituent is needed the fact remains that biphenyl is included in the definition of aryl in Sauerberg.

The Applicants arguments with regard to De la Brouse-Elwood are not persuasive either because as with Sauerberg, regardless of how De la Brouse-Elwood achieves the biphenyl substituent, it is included in the definition of aryl.

The Applicants have taken the position that if one of ordinary skill in the art wanted the term aryl to include the situation of one or more aromatic rings connected through a single bond, such a distinction should be specifically described in the definition of aryl. Both Pershadsingh and Elwood support this conclusion, as both references wanted aryl to include, for example, biphenyl, and both did so specifically.

This argument is not persuasive because a reference need not disclose what is well known in the art. In re MYERS, 161 USPQ 668 (CCPA 1969). Based upon the teachings of Pershadsingh et al., De la Brouse-Elwood, Lou et al. (US 2002/0082263 A1), Houze et al. (US 2002/0120137 A1), McGee et al. (US 2002/0169185 A1) and others that biphenyl is a well known aryl compound. Thus, one having ordinary skill in the art would reasonably expect that the “and the like” of Sauerberg includes biphenyl, which is an aryl compound having two aromatic rings connected with a single bond.

For the above reasons, the Examiner believes that the instant claims are prima facie obvious over Sauerberg et al. (WO 01/79150 A1) in view of Pershadsingh et al. (US 6,028,088) and De la Brouse-Elwood et al. (US 6,200,995 B1).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSALYND KEYS whose telephone number is (571)272-0639. The examiner can normally be reached on M, W, F 8 am-3:30 pm; T, Th 5:30 am-7 am & 9:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROSALYND KEYS/
Primary Examiner, Art Unit 1621

November 3, 2008